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Dated: January, 5, 2006 Signature: 

(Lenay Rogus)

Patent  
Docket No. 532552001100

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Andrew S. JANOFF et al.

Serial No.: 10/551,374

Filing Date: (Int'l) April 2, 2004

For: METHODS TO INDIVIDUALIZE  
COMBINATION THERAPY

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

The document numbers 2, 3, 9, and 16 listed on the attached Form PTO/SB/08a/b were cited in an International Search Report mailed on October 7, 2004, directed to a counterpart international or foreign application and have not been previously cited.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 532552001100.

Dated: January 4, 2006

Respectfully submitted,

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/551,374
				Filing Date	(Int'l) April 2, 2004
				First Named Inventor	Andrew S. JANOFF
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	532552001100

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	BARRIERE et al., Pharmacotherapy (1992) 12:397-402	
	2.	BEPLER et al., Cancer Research (1986) 46(7):3413-3419	
	3.	BLUMENTHAL et al., International Journal of Cancer (2004) 108:293-300	
	4.	BONNER and KOZELSKY, Cancer Chemother. Pharmacol. (1990) 39:109-112	
	5.	FREI et al., Clin. Cancer Res. (1998) 4:2027-2037	
	6.	HOFS et al., Anticancer Drugs (1994) 5:35-42	
	7.	International Search Report for PCT/US2004/010388, mailed on October 7, 2004, 5 pages	
	8.	KANZAWA et al., Int. J. Cancer (1997) 71(3):311-319	
	9.	OSAKI et al., Cancer Gene Therapy (2000) 7(2):300-307	
	10.	PEROU et al., Nature (2000) 406(6797):747-752	
	11.	SCHIMPFF, Support Care Cancer (1993) 1:15-18	
	12.	SHAH and SCHWARTZ, Clin. Cancer Res. (2001) 7:2168-2181	
	13.	SHLAES et al., Clin. Infect. Dis. (1993) 17:S527-S536	
	14.	SWAFFAR et al., Anti-Cancer Drugs (1995) 6:586-593	
	15.	TODD et al., J. Clin. Oncol. (1984) 2:986-993	
	16.	VANT VEER et al., Nature (2002) 415:530-536	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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sd-286089